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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Shizuo Akira

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EXAMINER

HAMA, JOANNE

ART UNIT

PAPER NUMBER

1632

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,212	Applicant(s) AKIRA ET AL.	
	Examiner JOANNE HAMA	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/12/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 12, 2008 has been entered.

Claims 3, 6, 7 are cancelled. Claims 1, 2, 4, 5, 8 are amended.

Claims 1, 2, 4, 5, 8, drawn to a TRAM knockout mouse, a cell obtained from the TRAM knockout mouse, and methods of screening for compounds, using said mouse and cell from said mouse, are under consideration.

Information Disclosure Statement

Applicant filed an Information Disclosure Statement (IDS) on August 12, 2008. The IDS has been considered.

Withdrawn Rejection

35 USC § 112, 2nd parag.

Applicant's arguments, see page 7 of Applicant's response, filed August 12, 2008, with respect to the rejection of claims 6, 7 have been fully considered and are

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persuasive. Applicant indicates that the claims are cancelled. The rejection of claims 6, 7 has been withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 4, 5, 8 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility, for reasons of record, November 1, 2007, May 12, 2008.

Applicant's arguments filed August 12, 2008 have been fully considered but they are not persuasive.

Applicant refers to US Patent 6,660,906 ('906) and indicates that the utility of the '906 patent is directly analogous to the claims of the instant application. The claims of the '906 patent are directed to a transgenic mouse with an endotoxin resistant phenotype produced by a homozygous inactivation of the Tpl2 gene. According to the '906 patent, uses for the endotoxin resistant transgenic mice include 1) method of identifying Tpl2 specific inhibitors of endotoxin shock and 2) a method of determining whether a compound that is known to inhibit Tpl2 activity in vitro also inhibits endotoxin shock in vivo (Applicant's response, page 5). In response, this is not persuasive. With regard to Applicant indicating that the mouse phenotypes between the '906 patent and the instant application are the same and thus, the utility of the claimed mice are the

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same, the mouse of the '906 patent is distinct from that of the instant invention because the mouse comprises a different knockout from that of the instant invention. As such, the pathology of the instant mouse is different from that of the '906 patent mouse and the use of the mouse in the '906 patent would not necessarily be the same as that of the instant mouse. With regard to Applicant indicating that the instant mouse can be used in the method of identifying inhibitors, it is noted that the method does not require the claimed knockout mouse. Rather, an artisan would screen for inhibitors or test the activity of putative inhibitors with a wild type mouse. As such, using the claimed mice in this context of a screen or seeing the effects of a putative inhibitor in them is not a specific and substantial use of the claimed mice. In addition to this issue, it is noted that given the phenotypes taught by the specification, the claimed mice are resistant to endotoxin shock. This means that the claimed mice are resistant to a disorder or a medical condition. It is unclear what use a mouse that is resistant to a disorder or medical condition has.

Thus, the claims remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 5, 8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record, November 1, 2007, May 12, 2008.

Applicant's arguments filed August 12, 2008 have been fully considered and they are persuasive in part.

Applicant indicates that as discussed above, one of skill in the art would have understood that the phenotype of the transgenic mice makes them useful within methods of identifying TRAM-specific inhibitors of endotoxin shock and/or method of determining whether a compound that is known to inhibit TRAM activity in vitro also inhibits endotoxin shock in vivo (Applicant's response, page 6). In response, as discussed above, screening for TRAM inhibitors and testing putative inhibitors of TRAM in vivo require wild type mice and do not require the instant knockout mice. In addition to this, the claimed mice are resistant to endotoxic shock. It is unclear what use a mouse resistant to a disease or disorder has. As such, Applicant does not provide an enabling use of the claimed mice. As such, the rejection as it applies to this issue remains.

Applicant indicates that the claims have been amended such that the claims are drawn to mice. In response, the rejection as it applies to issues of making knockout animals using ES cells from a wide species of animals is withdrawn.

Thus, the claims remain rejected.

Conclusion

No claims allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
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